

CLAIMS

1. A method of treating or preventing high-risk plaque, the method comprising:  
applying to a medical device an effective amount of a composition comprising  
5 a sex hormone, anti-hormone, sex-hormone agonist, steroid-hormone  
inhibitor/antagonist (partial or full), selective estrogen receptor modulator (SERM), or  
a combination thereof; and  
inserting the medical device into an area of a living organism that is or has a  
propensity to be affected by high-risk plaque.  
10
2. The method of claim 1, further comprising allowing at least a portion of the sex  
hormone, anti-hormone, sex-hormone agonist, steroid-hormone inhibitor/antagonist (partial or  
full), selective estrogen receptor modulator (SERM), or combination thereof, to gradually  
release from the medical device into the area of the living organism that is or has a propensity  
15 to be affected by the high-risk plaque, thereby treating or preventing the high-risk plaque.
3. The method of claim 1, wherein the composition comprises a sex hormone and  
the sex hormone comprises estrogen, progesterone, testosterone, dehydroepiandrostrone  
(DHEA), dehydroepiandrosteronesulfate (DHEA) or a combination thereof.  
20
4. The method of claim 1, wherein the medical device comprises a stent.
5. The method of claim 1, wherein the medical device comprises a catheter, a  
balloon catheter or a balloon.  
25
6. The method of claim 1, wherein the composition comprises a sex hormone and  
the sex hormone comprises estrogen.
7. The method of claim 6, wherein the medical device comprises a stent.  
30
8. The method of claim 6, wherein the medical device comprises a catheter.

9. The method of claim 1, wherein the composition comprises a sex-hormone agonist and the sex-hormone agonist comprises estradiol, estrone, ethinyl estradiol, conjugated equine estrogen, or a combination thereof.

5

10. The method of claim 1, wherein the composition comprises an anti-hormone and the anti-hormone comprises an anti-estrogen, Faslodex, an anti-androgen, cyproterone acetate, an anti-testosterone, or a combination thereof.

10 11. The method of claim 1, wherein the composition comprises a steroid-hormone inhibitor/antagonist (partial or full) and the steroid-hormone inhibitor/antagonist (partial or full) comprises aminoglutethimide, anastrozole, letrozole, or a combination thereof.

12. The method of claim 1, wherein the composition comprises a SERM and the  
15 SERM comprises a raloxifene, tamoxifen, tibolone, idoxifene, or a combination thereof.

13. The method of claim 1, wherein the affected area of the living organism comprises tissue, tubular organs, blood vessels, coronary or peripheral of organs, myocardium, skeletal, smooth muscles or a combination thereof.

20

14. The method of claim 1, wherein the effective dose of the composition comprises about 50 µg to about 1000 µg.

15 15. The method of claim 1, wherein the effective dose of the composition comprises about 50 µg to about 276 µg.

16. The method of claim 1, wherein the composition further comprises an antibody, oligonucleotide, antiproliferative, anticancer agent, growth factor, gene, antithrombotic agent thrombin inhibitor, antithrombogenic agent, thrombolytic agent, fibrinolytic agent, vasospasm inhibitor, calcium channel blocker, vasodilator, antihypertensive agent, antimicrobial agent, antibiotic, anti-lipid agent, inhibitor of surface glycoprotein receptors, antiplatelet agent, antimitotic, microtubule inhibitor, anti-secretory agent, actin inhibitor, remodeling inhibitor, antisense nucleotide, anti-metabolite, anticancer chemotherapeutic agent, anti-inflammatory steroid or non-steroidal anti-inflammatory agent, immunosuppressive agent, growth hormone antagonist, dopamine agonist, radiotherapeutic agent, peptide, protein, enzyme, extracellular matrix component, angiotensin-converting enzyme (ACE) inhibitor, free radical scavenger, chelator, antioxidant, anti-polymerase, antiviral agent, photodynamic therapy agent, gene therapy agent or combination thereof.

17. The method of claim 1, wherein the high-risk plaque comprises vulnerable plaque.

18. A local-delivery device for treating or preventing high-risk plaque in a living organism, the device comprising: a medical device at least partially coated with an effective dose of a composition comprising a sex hormone, anti-hormone, sex-hormone agonist, steroid-hormone inhibitor/antagonist (partial or full), selective estrogen receptor modulator (SERM), or a combination thereof, the local-delivery device being suitable for treating or preventing high-risk plaque.

19. The device of claim 18, wherein the medical device comprises a stent.

20. The device of claim 19, wherein the composition comprises a sex hormone, and the sex hormone comprises estrogen.

21. The device of claim 18, wherein the medical device comprises a catheter, a balloon catheter or a balloon.

22. The device of claim 18, further comprising a platform, natural carrier, pharmaceutical agent, polymer or combination thereof at least partially encompassing the composition, thereby allowing for gradual release of the composition therefrom when the medical device is inserted into a living organism.

5

23. The device of claim 18, wherein the medical device is at least partially coated with a polymer and the polymer comprises a biostable polymer, a bioabsorbable polymer, biodegradable, bioerodable or a combination thereof.

10

24. The device of claim 18, wherein the effective dose of the composition comprises about 50 µg to about 1000 µg.

25. The device of claim 18, wherein the effective dose of the composition comprises about 50 µg to about 276 µg.

15

26. The device of claim 18, wherein the effective dose of the composition comprises about 2.4 µg to about 3.2 µg per 1 mm<sup>2</sup> of medical device.

27. The device of claim 18, wherein the composition further comprises a sex hormone, anti-hormone, sex-hormone agonist, steroid-hormone inhibitor/antagonist (partial or full), selective estrogen receptor modulator (SERM) or a combination thereof.

20

28. The device of claim 18, wherein the composition further comprises an antibody, oligonucleotide, antiproliferative, anticancer agent, growth factor, gene, antithrombotic agent thrombin inhibitor, antithrombogenic agent, thrombolytic agent, fibrinolytic agent, vasospasm inhibitor, calcium channel blocker, vasodilator, antihypertensive agent, antimicrobial agent, antibiotic, anti-lipid agent, inhibitor of surface glycoprotein receptors, antiplatelet agent, antimitotic, microtubule inhibitor, anti-secretory agent, actin inhibitor, remodeling inhibitor, antisense nucleotide, anti metabolite, anticancer chemotherapeutic agent, anti-inflammatory steroid or non-steroidal anti-inflammatory agent, immunosuppressive agent, growth hormone antagonist, dopamine agonist, radiotherapeutic agent, peptide, protein, enzyme, extracellular matrix component, angiotensin-converting enzyme (ACE) inhibitor, free radical scavenger, chelator, antioxidant, anti polymerase, antiviral agent, photodynamic therapy agent, gene therapy agent or combination thereof.

29. A method of treating high-risk plaque in a living organism, the method comprising:  
applying an effective dose of a composition comprising estrogen, estradiol or a derivative thereof to a stent by chemical or physical bonding;  
placing the stent at or near high-risk plaque; and  
releasing the estrogen, estradiol or derivative thereof.

30. The method of claim 29, wherein applying an effective dose of the composition to the stent comprises immersing the stent in a solution comprising estrogen, estradiol or a combination thereof and allowing the stent to dry.

31. The method of claim 29, wherein the effective dose of the composition comprises about 50 µg to about 1000 µg.

32. The method of claim 29, wherein the effective dose of the composition comprises about 50 µg to about 276 µg.

33. The method of claim 29, wherein the effective dose comprises about 2.4  $\mu\text{g}$  to about 3.2  $\mu\text{g}$  of the composition per 1  $\text{mm}^2$  of stent.

34. The method of claim 29, wherein the chemical bonding comprises at least  
5 partially encompassing the composition with a platform, natural carrier, pharmaceutical agent, polymer or combination to allow for gradual elution of the composition therefrom.

35. The method of claim 34, wherein the platform at least partially encompasses the composition and the platform comprises silicon carbide, carbon, diamond, diamond-like  
10 coating, polytetrafluoroethylene, hylauronic acid, polyactone or a combination thereof.

36. The method of claim 34, wherein the natural carrier at least partially encompasses the composition and the natural carrier comprises collagen, laminen, heparin, fibrin, a naturally occurring substance that absorbs to cellulose or a combination thereof.

15

37. The method of claim 34, wherein the pharmaceutical agent at least partially encompasses the composition and the pharmaceutical agent comprises polyurethane, segmented polyurethane, poly-L-lactic acid, cellulose ester, polyethylene glycol, polyphosphate esters or a combination thereof.

20

38. The method of claim 34, wherein the polymer at least partially encompasses the composition and the polymer comprises a biostable polymer, a bioabsorbable polymer or a combination thereof.

25

39. The method of claim 29, wherein the high-risk plaque comprises vulnerable plaque.